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AF/165-4

Docket No. 0263-4047

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Shuji SUMIDA et al.

Group Art Unit: 1654

Serial No.: 09/622,487

Examiner: RUSSELL, Jeffrey E.

Filed: August 17, 2000

For: PROTEIN-FREE FORMULATIONS

EXPRESS MAIL CERTIFICATE

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Sir:

SIR

Further to the Interview between Applicants' representatives and the Examiner held on [redacted] July 2, 2003, Applicants submit with this communication a table summarizing experiments that Applicants propose to perform for a §132 Declaration to overcome the pending obviousness rejections (see Appendix 1). It is Applicants' understanding that the Examiner has kindly agreed to review any proposed experiments before they are performed in order to ensure that they properly address the obviousness issues.

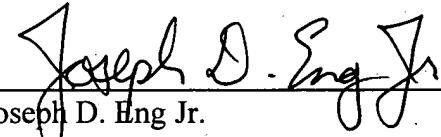
Because the experiments take time to perform, Applicants would greatly appreciate a prompt response from the Examiner regarding the suitability of the proposed experiments. If the Examiner has any questions regarding the experiments or any other aspect of this case, he is invited to contact the undersigned at the number provided.

The Commissioner is hereby authorized to charge any fees which may be required for consideration of this paper to Deposit Account No. 13-4500, Order No. 0263-4047. A DUPLICATE OF THIS DOCUMENT IS ATTACHED.

Respectfully submitted,
MORGAN & FINNEGAN, L.L.P.

Dated: November 14, 2003

By:


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Appendix 1

Applicants intend to conduct a comparative test between Test Sample 1 or 2 with Example 2 of Tsuji et al. and Example 2 of JP4-77436A (see table below) at a temperature of 40 °C for two weeks. For the Examiner's convenience, compositions of the present invention, Tsuji and JP 4-77436A are also summarized.

| | Document | Formulation | Polysorbate 20 | Polysorbate 80 | G-CSF | Phosphate buffer | pH | mannitol | NaCl | HSA |
|---|----------------------------|-------------|----------------|----------------|-----------|------------------|--------|----------|----------|-----|
| | Present Invention | Table 1 | 0.1 mg/mL | | 250 µg/mL | 25 mM | pH 4~8 | 30 mg/mL | | |
| | Tsuji et al. (USP 5202117) | Example 2 | | 0.1 mg/mL | 100 µg/mL | 10 mM | pH 7.0 | | Isotonic | |
| | JP 4-77436A | Example 2 | | 0.1 mg/mL | 100 µg/mL | 10 mM | pH 7.0 | | Isotonic | |
| A | Test Sample 1 | | 0.1 mg/mL | | 100 µg/mL | 10 mM | pH 6.8 | | Isotonic | |
| B | Test Sample 2 | | | 0.1 mg/mL | 100 µg/mL | 10 mM | pH 6.8 | | Isotonic | |